IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES TO ETHICON WAVE 1 CASES	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

MEMORANDUM IN SUPPORT OF MOTION TO EXCLUDE CERTAIN GENERAL OPINIONS OF BRUCE ROSENZWEIG, M.D.

Defendants Ethicon, Inc. and Johnson & Johnson (hereinafter "Defendants") submit this memorandum in support of their motion to exclude certain opinions of Bruce Rosenzweig, M.D., with respect to the cases set forth in Exhibit A.

INTRODUCTION

Dr. Rosenzweig is a pelvic surgeon and urogynecologist with experience in the surgical treatment of stress urinary incontinence ("SUI") and pelvic organ prolapse ("POP"), as well as the removal of sling systems. Ex. B, curriculum vitae. Dr. Rosenzweig intends to provide general opinions about TVT, TVT-O, TVT-Abbrevo, TVT Exact and TVT Secur (collectively "the TVT Devices"), as well as Prosima. Ex. C-G, Expert Reports.[1] As set forth below, the Court should preclude Dr. Rosenzweig from testifying about matters that are beyond his expertise, that are irrelevant, that are unreliable, that are prejudicial, and/or that would confuse or mislead the jury.

[1] Plaintiffs adopted five different reports attributable just to Dr. Rosenzweig's opinions about TVT and TVT-O *See* Ex. 1-5 to Ex. C hereto. Because most of Dr. Rosenzweig's opinions about the TVT Devices are the same, citations in this brief are generally limited to one of those reports.

LEGAL ARGUMENT

Defendants incorporate by reference the standard of review for *Daubert* motions set forth by the Court in *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 701 (S.D.W. Va. 2014).

I. The Court should preclude Dr. Rosenzweig from testifying that non-synthetic mesh procedures are a safer alternative for the surgical treatment of SUI and POP and/or that Defendants' devices are less safe than those alternatives.[2]

Dr. Rosenzweig believes that "traditional surgeries like the Burch and pubovaginal slings" lead to fewer complications than TVT Devices for the surgical treatment of SUI, and that traditional native tissue repairs are a safer alternative to Prosima for the surgical treatment of POP. *See* Ex. C-2, TVT Report No. 2, pp. 7-10, 101-02; Ex. G, Prosima Report at 9-10, 42-45. Any alleged comparative benefits of traditional approaches to treat SUI and POP are not even relevant to Plaintiffs' design defect claims, because these approaches are not a medical device.

By its very nature, a safer alternative must be another product. As this Court has stated:

> [A]n "alternative design must not be an altogether essentially different product." *Torkie*, 739 F.Supp. 2d at 900. Stated differently, "an alternative design is not reasonable if it alters a fundamental and necessary characteristic of the product." *Id.; see also Caterpillar, Inc. v. Shears*, 911 S.W.2d 379, 385 (Tex.1995) (noting, in design defect context, that "[a] motorcycle could be made safer by adding two additional wheels and a cab, but then it is no longer a motorcycle."); *Kimball v. RJ Reynolds Tobacco Co.*, No. C03–664, 2006 WL 1148506, *3 (W.D.Wash. Apr. 26, 2006) (holding that a plaintiff "cannot point to an entirely different product as an alternative design").

[2] This argument applies to the following Plaintiffs in which applicable state law requires a plaintiff to prove the availability of a feasible, safer alternative product: Banks (Ala.--*McMahon v. Yamaha Motor Corp., USA*, 95 So. 3d 769, 772 (Ala. 2012); Blake & Springer (La.--La. Rev. Stat. § 9:2800.56; *Reeves v. AcroMed Corp*, 44 F.3d 300, 308 (5th Cir. 1995)); Bollinger (Wis.--Wis. Stat. Ann. § 895.047(1)(a)); Dimock (Utah--*English v. Suzuki Motor Co.*, 1997 U.S. App. LEXIS 19865, at *11 (10th Cir. 1997)); Free (Ind.-- *Piltch v. Ford Motor Co.*, 778 F.3d 628, 632 (7th Cir. 2015); *Whitted v. Gen. Motors Corp.*, 58 F.3d 1200, 1206 (7th Cir.1995); *Simmons v. Philips Elecs. N. Am. Corp.*, 2015 WL 1418772, at *10 (N.D. Ind. Mar. 27, 2015)); Guinn & Vignos-Ware (Ohio--OHIO REV. CODE § 2307.75(F); *McGrath v. Gen. Motors Corp.*, 26 F. App'x 506, 510 (6th Cir. 2002)); Hendrix, Long, Riddell & Shepherd (Ky.--*Toyota Motor Corp. v. Gregory*, 136 S.W.3d 35, 42 (Ky. 1991)); Johnson (Minn.--*Kapps v. Biosense Webster, Inc.*, 813 F. Supp. 2d 1128, 1161 (D. Minn. 2011)); Jones (Mich.--Mich. Comp. Laws § 600.2946(2); *BMW Croske of N. Am. Inc.*, 532 F.3d 511, 515-16 (6th Cir. 2008)); Lankston (Tex.--*Hernandez v. Tokai Corp.*, 2 S.W.3d 251, 256, 258 (Tex. 1999); Wolfe (N.Y.-- *Sita v. Danek Med., Inc.*, 43 F. Supp. 2d 245, 258 (E.D.N.Y. 1999); and Zoltowski (S.C.-- *Branham v. Ford Motor Co.*, 701 S.E.2d 5, 16 (S.C. 2010)).

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Hines v. Wyeth, 2011 WL 1990496, at *8 (S.D. W. Va. May 23, 2011). *See also Caterpillar, Inc.*, 911 S.W.2d at 385 (finding that the law of product liability does not "impose liability in such a way as to eliminate whole categories of useful products from the market"). Although in *Hines*, the Court indicated that this presented a jury question, here no reasonable mind could conclude that traditional surgical approaches are *products*.

The notion that the traditional surgical procedures are safer alternatives to Ethicon's products is premised on the assumption that all mesh products are unsafe. Such an "argument . . . really takes issue with the choice of treatment made by [the patient]'s physician, not with a specific fault of" the device. *Theriot v. Danek Med., Inc.*, 168 F.3d 253, 255 (5th. Cir. 1999) (surgical alternative to pedicle screw could not be considered). As explained in *Schmidt v. C.R. Bard, Inc.*, 2013 WL 3802804, at *2 (D. Nev. July 22, 2013), "non-mesh repair is not an alternative design and does not meet Plaintiff's burden to support" a design-defect claim. *See also Caterpillar, Inc. v. Shears*, 911 S.W.2d 379, 385 (Tex. 1995) (noting in design defect context that "[a] motorcycle could be made safer by adding two additional wheels and a cab, but then it is no longer a motorcycle" and that product liability law does not "impose liability in such a way as to eliminate whole categories of useful products from the market").

In reality, Plaintiff takes issue with the choice of her physician to recommend a medical device (ie. TVT) rather than another form of non-device surgery (ie. pubovaginal slings). But that choice depends on a number of factors beyond Ethicon's control, including the experience and training of the physician, which is why the law trusts the physician with that decision and does not make the decision for him by allowing a jury to substitute its judgment. Dr. Rosenzweig's testimony about any alleged comparative benefits of surgical procedures that do not utilize a medical device is irrelevant and inadmissible.

II. The Court should preclude Dr. Rosenzweig from providing design opinions and testifying that other synthetic mesh devices are safer alternatives for the surgical treatment of SUI or POP.

The Court should exclude Dr. Rosenzweig's other product design opinions. For instance, without explaining what he thinks Ethicon should have done, Dr. Rosenzweig states that Ethicon "fail[ed] to design the TVT in a way that it could be properly tensioned." Ex. C-1, TVT Report No. 1, p. 61. He also suggests that devices with lighter-weight, larger-pore mesh are preferable alternatives to Ethicon's devices at issue. *See id.* at 48-53; Ex. G, Prosima Report, pp. 28-32. The Court should exclude such opinions because Dr. Rosenzweig is not qualified to offer them, he has not indicated with reasonable medical certainty that other mesh products are safer than and as efficacious as Ethicon's devices at issue, and his opinions are unreliable.

A. Dr. Rosenzweig is not qualified.

Dr. Rosenzweig is not qualified to provide design opinions. He has no expertise in biomaterials or polymer chemistry. Ex. H, Rosenzweig 11/4/13 Dep. Tr. 56:13-23. Further, he has not conducted studies to compare the weight and pore size of the mesh at issue to the mesh in other commercially available devices. He has never treated a patient for SUI or POP with a lighter-weight, larger-pore mesh and cannot identify anyone else who ever has.

This Court has repeatedly found that other pelvic surgeons "lack[] the 'knowledge, skill, experience, training or education' as to product design that *Federal Rule of Evidence 702* requires" and that experience removing mesh devices, observing complications, and reviewing internal company documents do not render them qualified to provide opinions concerning design. *Tyree v. Boston Scientific Corp.*, 54 F. Supp. 3d 501, 561 (S.D. W. Va. 2014); *Wilkerson v. Boston Scientific Corp.*, 2015 WL 2087048, at *15 (S.D. W. Va. May 5, 2015); *Cisson v. C. R.*

Bard, Inc., 948 F. Supp. 2d 589, 612-13 (S.D. W.Va. 2013). The Court should extend that ruling to prevent Dr. Rosenzweig from providing such testimony here.

B. Dr. Rosenzweig's opinions are uncertain and unreliable.

In any event, Dr. Rosenzweig's opinions on this subject are otherwise unreliable. First, in his Prosima report, Dr. Rosenzweig merely states that "Ethicon had alternatives to including the heavyweight small pore GYNEMESH PS in the PROSIMA," and that "[t]hese options *may* have mitigated some of the deformation and resultant adverse events associated with the GYNEMESH PS." Ex. G, Prosima Report at 35. (emphasis added). When pressed about these opinions during his deposition, Dr. Rosenzweig reiterated this uncertainty.

Dr. Rosenzweig has suggested that the mesh in the devices at issue should be replaced with Ultrapro mesh used in non-SUI and non-POP devices, because Ultrapro weighs less and is more macroporous. *See id.* at 33, 52; Ex. C-2, TVT Report No. 2 at 33, 52; Ex. I, Rosenzweig 9/22/15 Dep. Tr. 154:9-155:2. Although Dr. Rosenzweig claims that Ultrapro is less susceptible to complications than Gynemesh PS and Prolene (*see id.* at 112:8-112:14), it is a logical fallacy for him to conclude that, because Ultrapro has fewer complications, it is a feasible alternative design.

In *Conklin v. Novartis Pharm. Corp.*, 2012 U.S. Dist. LEXIS 136428 (E.D. Tex. Sept. 18, 2012), the federal district court rejected similarly flawed logic. The plaintiff there alleged that she suffered an adverse event following ingestion of the cancer medication Zometa. She designated an expert who sought to opine that a lower dose of Zometa would have prevented the adverse event. As the court aptly noted, the opinion was a logical fallacy because the expert lacked sufficient data to show that the lower dose he proposed would fight the plaintiff's cancer effectively. *See id.* at *26-*27. As the court explained:

> The analytical gap, in Dr. Marx's opinion is demonstrated by setting out his premises and conclusions:
>
> > **Premise:** Studies show that a certain regimen of Zometa helps treat cancer-related bone conditions, but may cause ONJ.
> >
> > **Premise:** Other studies show that less Zometa will result in less ONJ.
> >
> > **Conclusion:** A regimen using less Zometa will help treat cancer-related bone conditions.
>
> This is a classic logical fallacy—an irrelevant conclusion.
>
> It is not helpful to the finder of fact for Dr. Marx to state that a drug used to fight cancer-related diseases has a particular negative side effect, and that reducing the dosage and/or frequency of that drug will reduce the occurrence of the negative side effect. Rather, Dr. Marx must also provide some factual support that reducing the dosage and/or frequency of that drug will not only reduce the occurrence of the negative side effect, but will also be effective at fighting cancer-related diseases. Unfortunately, Dr. Marx offers no evidence as to the efficacy of a reduced Zometa regimen, and he does not explain from where he draws his naked conclusion regarding efficacy— certainly, it is not in either of the articles he cites.

Id.

Dr. Rosenzweig engages in precisely the same illogical analysis here as Dr. Marx did in *Conklin*. For instance, Dr. Rosenzweig opines that the Prolene mesh's pores are too small, the mesh weighs too much, and the mesh contains too great a volume of polypropylene. He then cites to a small number of studies indicating that lighter-weight, larger-pore mesh, and mesh with a smaller volume of polypropylene, results in fewer complications when used for purposes *other than* the treatment of SUI. But Dr. Rosenzweig cites *no* studies showing that the alternative mesh is equally as effective as TVT Devices for the treatment of stress urinary incontinence. No such studies exist.

Only one study to date—the "Okulu study"—has examined the use of Ultrapro in the treatment of SUI. *See* Ex. I, Rosenzweig 9/22/15 Dep. Tr. 174:20-177:2. The Okulu study did

not compare Ultrapro (or any of the other lighter-weight, larger-pore meshes) to TVT. *See id.* at 114:22-114:25. In fact, the Okulu study involved a different and more invasive type of surgery—one that did not employ the TVT retropubic procedure. *See id.* at 115:1–117:8. Moreover, whereas TVT surgery is an outpatient procedure, the patients in the Okulu study spent an average of two days each in the hospital. *See* Ex. J, Okulu, E., Kayigil, O., Aldemir, M. & Onen, E., *Use of three types of synthetic mesh material in sling surgery: A prospective randomized clinical trial evaluating effectiveness and complications*, SCAND. J. UROL., 47:217-224, 220 (2013).

Additionally, Dr. Rosenzweig cannot identify the polypropylene volume at which efficacy can be obtained and adverse events avoided. His inability to do so renders his opinion unreliable and speculative. As the court reasoned in *Conklin*:

> Dr. Marx does not explain what specific dosage and/or frequency schedule would achieve similar results for fighting cancer-related diseases. By way of analogy, studies might show that a dose of two aspirin every four hours alleviates a headache, but results in a 20% risk of stomach bleeding. One might hypothesize that a safe alternative design would include reducing the dosage or increasing the interval between doses. But there is a significant analytical gap between this hypothetical alterative dosage/frequency regime, and actually demonstrating that similar headache relief could be obtained.

2012 U.S. Dist. LEXIS 136428 at *27. Just like the expert in *Conklin*, Dr. Rosenzweig cannot identify the amount of mesh that he believes is both biocompatible and effective for the treatment of SUI and POP. *See* Ex. I, Rosenzweig 9/22/15 Dep. Tr. 182:2-185:12.

In addition to being a logical fallacy, Dr. Rosenzweig's Ultrapro opinion veers into hypocrisy. One of Dr. Rosenzweig's main complaints regarding the use of Prolene mesh for the treatment of SUI is his allegation that Ethicon lacked sufficient "long-term data"—which he defines as data extending beyond five years. *See id.* at 84:11-13. Yet he concedes that Ultrapro does not have "long-term data" on which to measure its safety and efficacy. *Id.* at 185:16-20.

According to Dr. Rosenzweig, "I would like to see more data on Ultrapro," "I don't think we have enough information" about Ultrapro, and "I don't think it has been studied long enough." Ex. K, Rosenzweig 7/13/15 Dep. Tr. 174:13-17, 198:8-13. Dr. Rosenzweig cannot have it both ways. He cannot declare that Prolene is defective due to a lack of "long-term data" while simultaneously declaring that Ultrapro is a safer and feasible alternative design in the absence of the same "long-term data."

In fact, Dr. Rosenzweig has acknowledged his uncertainty about the feasibility of Ultrapro given the lack of research concerning its use in the treatment of SUI:

> I used Ultrapro as an example since that is an example that is on the market. Obviously in order to justify the use of a polypropylene-based product like Ultrapro, there would have to be a significant amount of research to be able to make sure that the amount of polypropylene that's leftover in Ultrapro, it is large -- a lighter weight, larger pore, smaller filament size is "biocompatible" with tissue.
>
> If you look at a single suture of polypropylene, that is probably below the minimal amount of polypropylene that is biocompatible with the body, just like when you look at flu vaccines, a flu vaccine has heavy metals in it, such as mercury and others. There is a minimal amount of -- of things like heavy metals and other toxic substances that is still biocompatible, even though at higher levels it becomes bioincompatible.
>
> And, so, therefore, there would need to be a significant amount of research to look at the -- whether the amount of polypropylene in Ultrapro is still at the level of biocompatibility. The research does seem to show that it is, as we've talked about before in other depositions, but that would also need to have, you know, a significant amount of research to be able to say if that is the case.

Ex. I, Rosenzweig 9/22/15 Dep. Tr. 180:17-181:18.

In the absence of any evidence demonstrating that Ultrapro is as efficacious as Prolene or Gynemesh PS, the Court should preclude Dr. Rosenzweig from opining that Ultrapro is a feasible design alternative. Neither the scientific literature nor logic supports such an opinion. *See also* Ex. L, *In re AlloDerm Litigation,* Case Code 295, N.J. Superior Court of Middlesex

County (Aug. 14, 2015), at 22 (rejecting challenge to hernia repair product because plaintiffs failed to "prove with empirical evidence or reliable data that the alternative is actually safer and there was evidence it [the proposed alternative design to the hernia repair product] was safer at the time of manufacture").

III. The Court should limit Dr. Rosenzweig's product warning opinions.

Dr. Rosenzweig also claims that Ethicon failed to provide adequate warnings to physicians and patients about the purported risks associated with the devices at issue. *See* Ex. C-1, TVT Report No. 1, pp. 20-24, 53-72, 85-97; Ex. G, Prosima Report, pp. 45-50. The Court should limit these opinions for the reasons below.

A. Warnings about the frequency, severity, and duration of possible adverse events.

In his reports, Dr. Rosenzweig suggests that Ethicon minimized and "'underestimated' the frequency and severity of the risks" included in the IFUs. Ex. C-1, TVT Report No. 1, pp. 76, 81; Ex. G, Prosima Report, p. 47. Courts have routinely found that a manufacturer's duty to warn does not include providing incidence, severity, and frequency rates of a particular adverse event. *See, e.g., Smith ex rel. v. Wyeth Labs. Inc.*, 1986 WL 720792, at *9-10 (S.D. W. Va. Aug. 21, 1986) (noting that "[t]he plaintiff cites no authority for the proposition that a drug manufacturer has a duty to warn prescribing physicians of the rate of adverse reactions," and that "[a]s a practical matter, this would be extremely difficult, perhaps impossible"); *Calabrese v. Trenton State Coll.*, 392 A.2d 600, 604 (N.J. App. Div. 1978) ("Plaintiff's central argument that a drug manufacturer's warnings must, as a matter of law, include not only information concerning undesirable side effects of the drug it is marketing but, as well, statistical information concerning the incidence of the condition for which the drug can be used, is without merit"); *Hurley v. Lederle Lab.*, 651 F. Supp. 993, 1002-03 (E.D. Tex. 1986), *rev'd on other grounds*,

863 F.2d 1173 (5th Cir. 1989); *Percival v. Am. Cyanamid Co.*, 689 F. Supp. 1060, 1063-64 (W.D. Okla. 1987); *Ames v. Apothecon, Inc.*, 421 F. Supp. 2d 566, 573-74 (D. Md. 2006); *Alston v. Caraco Pharm., Inc.*, 670 F. Supp. 2d 279, 286-87 (S.D.N.Y. 2009); *McDowell v. Eli Lilly & Co.*, 2014 U.S. Dist. LEXIS 157819 (S.D.N.Y. Nov. 7, 2014).

These decisions show that the absence of incidence, severity, and frequency rates of adverse events does not render a warning insufficient. Accordingly, the Court should exclude any testimony from Dr. Rosenzweig that Ethicon's IFUs were deficient for failing to include incidence, severity, or frequency rates concerning a particular adverse event.

B. Opinions about the appropriateness of the devices for certain patient populations are irrelevant and unreliable.

Dr. Rosenzweig criticizes Ethicon for marketing TVT Devices to women who are obese, elderly, young and active, or with "certain pre-existing conditions." Ex. C-1, TVT Report No. 1, pp. 82-86. In his Prosima report, Dr. Rosenzweig states that "certain patient populations were more likely to experience adverse outcomes" from the device, but he bases his opinions on Prolift, rather than Prosima, and he does not identify the specific types of patient populations. Ex. G, Prosima Report, p. 50. To the extent that Dr. Rosenzweig intends to testify about patient populations of which each respective Plaintiff is not a member, any such testimony is irrelevant and unhelpful to the jury and therefore inadmissible. *See* Fed. R. Evid. 402, 702.

Moreover, the Court should exclude Dr. Rosenzweig's opinion because it is nothing more than a narrative summary of Ethicon documents and employee deposition testimony. For example, Dr. Rosenzweig cites e-mails and deposition testimony of Ethicon's medical director, Dr. Kirkemo, to show that "obese people tend – not to do as well." Ex. C-1, TVT Report No. 1, pp. 82-83. Similarly, Dr. Rosenzweig block-quotes Dr. Kirkemo's testimony to demonstrate efficacy problems for younger and older women. *See id.* Dr. Rosenzweig then concludes,

without any explanation, that the TVT Devices are not effective for special patient populations and that Ethicon should have informed physicians of these patient variations. *Id.*

These opinions are hardly expert in nature. As many courts have recognized, "[h]aving an expert witness simply summarize a document (which is just as easily summarized by a jury) with a tilt favoring a litigant, without more, does not amount to expert testimony." *In re Prempro Prods. Liab. Litig.*, 554 F. Supp. 2d 871, 887 (E.D. Ark. 2008). The Court should preclude Dr. Rosenzweig from doing so here.

To the extent that Dr. Rosenzweig intends to testify that a device at issue was not appropriate for a particular Plaintiff's specific population, the Court also should exclude that testimony. Dr. Rosenzweig's report does not set forth a basis for that opinion. Any such opinion is therefore unfounded, unreliable, and inadmissible. *See* Fed. Evid. 702. In *Huskey*, Dr. Rosenzweig sought to testify that Ethicon inappropriately promoted the product as appropriate for all patients. 29 F. Supp. 3d at 705. This Court, however, found that "much of this opinion is not relevant to [the plaintiff's] case and should be excluded." *Id.* The Court went further and also precluded Dr. Rosenzweig from testifying about appropriateness of the product to the plaintiff's specific population. *See id.* The Court reasoned that Dr. Rosenzweig's opinion was merely based upon his review of a document, and "[t]he jury is capable of reading that document itself." *Id.* For these same reasons, the Court should preclude Dr. Rosenzweig from offering such testimony here.

IV. The Court should preclude Dr. Rosenzweig from testifying about alleged mesh degradation and other biomaterials opinions.

Although he has no experience as a biomaterials expert or a polymer scientist (Ex. H, 11/4/13 Dep. Tr. 56:13-23), Dr. Rosenzweig makes a number of assertions about biomaterials opinions that are unreliable, irrelevant, and/or otherwise improper.

A. Degradation

The Court should exclude Dr. Rosenzweig's general opinion that Ethicon's devices at issue are defective because their mesh supposedly degrades *in vivo* and is subject to fraying and particle loss. *See* Ex. C-2, TVT Report No. 2, pp. 13-22, 36-48; Ex. G, Prosima Report, pp. 14-22. Dr. Rosenzweig's opinion is unreliable because neither he nor any of Plaintiffs' other experts can connect the alleged degradation, fraying, and particle loss to adverse events experienced by women.

In *Huskey*, the Court allowed Dr. Rosenzweig to testify about these topics. 29 F. Supp. 3d at 707-09. Thereafter, however, Dr. Rosenzweig has admitted that there are no studies connecting degradation, fraying, or particle loss to an adverse event. *See* Ex. I, 9/22/15 Rosenzweig Dep. Tr. at 251:18-256:4. The best that he can come up with is a case report where mesh was explanted and allegedly showed degradation, fraying, or particle loss. *See id.* That does not constitute reliable evidence of causation, however. *See, e.g.*, *Turner v. Iowa Fire Equip. Co.*, 229 F.3d 1202, 1209 n.5 (8th Cir. 2000) ("Case reports are generally not considered reliable evidence of causation.") (collecting cases); *Soldo v. Sandoz Pharm. Corp.*, 244 F. Supp. 2d 434, 537 (W.D. Pa. 2003) ("The great weight of authority—and the most current authority—squarely rejects the use of . . . case reports for the purpose of establishing general causation.").

Dr. Rosenzweig's opinion about degradation are premised on an improper *post hoc ergo propter hoc* logical fallacy. Dr. Rosenzweig takes two premises—(1) Prolene and Gynemesh PS mesh are subject to degradation, fraying, and particle loss, and (2) women complain of pain following the implantation of Ethicon's devices—and he then attempts to connect the two events, suggesting that *because* mesh allegedly degrades, frays, and loses particles, women implanted with the mesh must experience pain. That is, Dr. Rosenzweig impermissibly assumes the existence of a causal connection between his two posited premises.

B. Cytotoxicity

In reports, Dr. Rosenzweig opines that Ethicon did not act as a reasonable medical device manufacturer because it failed to inform physicians and their patients about the "potential for cytotoxicity or cell death." Ex. C-1, TVT Report No. 1, p. 65; Ex. G, Prosima Report, pp. 14, 17, 27. The Court should preclude Dr. Rosenzweig, who has never performed any cytotoxicity testing of polypropylene (Ex. H, Rosenzweig 11/4/13 Dep. Tr. 222:4-6), from testifying that polypropylene mesh is cytotoxic or that Ethicon should have warned physicians of toxicity testing.

In *Huskey*, the Court allowed Dr. Rosenzweig to testify about cytotoxicity. 29 F. Supp. 3d at 705. Subsequent to that ruling, however, Dr. Rosenzweig has admitted that there are no clinical studies reporting that any alleged Prolene cytotoxicity causes any complications in women. *See* Ex. I, Rosenzweig 9/22/15 Dep. Tr. 256:5-257:14. When asked during his deposition if he was "aware of any studies that report for Prosima or Gynemesh PS in women that complications were deemed to be due to cytoxicity," Dr. Rosenzweig responded: "Not that I recall." Ex. K, Rosenzweig 7/13/15 Dep. Tr. 195:16-20. He also testified that "I can't tell you what the general consensus is" within the medical field about whether the mesh is cytotoxic. *Id.* at 208:23-209:8.

Further, the sole basis for Dr. Rosenzeig's opinion about cytoxicity is an Ethicon risk assessment document that states only that "there is some evidence to *suggest* that the PP [*i.e.*, polypropylene] mesh from the sterile Ulmsten device *may* have cytotoxic *potential*." Ex. N, Excerpt from Cytotoxicity Risk Assessment for the TVT Ulmsten Device (Aug. 8, 1997) at 259 (emphasis added). That risk assessment concludes that "this clinical data provides important evidence that the cytotoxicity of the PP mesh observed in vitro does *not* translate into any clinical significance or adverse patient outcomes." *Id.* (emphasis added). In other words, the

risk assessment confirmed that cytotoxicity was *not* an issue of significance for patients implanted with polypropylene mesh. In fact, not even Dr. Uwe Klinge, Plaintiffs' biomaterials expert, opines that Prolene is cytotoxic, and Dr. Rosenzweig merely discusses the "potential." Ex. C-1, TVT Report No. 1, p. 65.

C. MSDS Sheet

The Court should further preclude Dr. Rosenzweig from suggesting that Defendants' mesh at issue should not be used in the vagina on the basis of the mesh MSDS sheet, which suggests that it is incompatible with "strong oxidizers" such as chlorine and nitric acid. *Id.* at 61-64; Ex. G, Prosima Report, pp. 35-39. The MSDS is for "polypropylene resin," not polypropylene and certainly not Prolene, which is a specially formulated form of polypropylene with antioxidants added. Ex. O, ETH.MESH.02026591. The MSDS does *not* forbid implantation in humans, and in fact, states: "No epidemiological studies or case reports suggest any chronic health hazards from long-term exposure to polypropylene decomposition products below the irritation level." *Id.*[3] It thus provides no support for the opinions expressed. Dr. Rosenzweig has offered no information at all on this topic that would be helpful to the jury.

Further, this is an area far beyond Dr. Rosenzweig's qualifications as a urogynecologist, and he has performed no methodological analysis of this claim. *See also Turner v. Iowa Fire Equip. Co.*, 229 F.3d 1202, 1209 (8th Cir. 2000) (suggesting expert's ignorance of the tests utilized to formulate MSDS diminished reliability of MSDS); *Moore v. Ashland Chem. Inc.*, 151 F.3d 269, 278 (5th Cir. 1998) (same); *Ingram v. Solkatronic Chem., Inc.*, No. 04-CV-0287, 2005 U.S. Dist. LEXIS 38304, at *22-23 (N.D. Okla. Dec. 28, 2005) (citing *Turner* and *Moore* and

[3] Under federal law, MSDS sheets do not apply to products regulated by the FDA. 29 C.F.R. § 1910.1200(b)(6)(vii).

excluding expert opinion under *Daubert* where expert opinion largely based on information in MSDS, but expert had no knowledge of how the MSDS was generated).

V. The Court should preclude Dr. Rosenzweig from testifying about duties allegedly owed by a manufacturer.

Dr. Rosenzweig makes a number of opinions about duties allegedly owed by Ethicon as a medical device manufacturer that are well outside of Dr. Rosenzweig's expertise. Dr. Rosenzweig is not qualified to provide such testimony, and his opinions are unreliable.

A. Testing

Dr. Rosenzweig suggests that Ethicon did not perform adequate testing and studies. *See, e.g.*, Ex. C-1, TVT Report No. 1, pp. 61-65; Ex. G, Prosima Report, pp. 18-21, 36. In fact, the TVT is one of the most-tested medical devices ever made. In precluding Dr. Rosenzweig from offering similar testimony, this Court found that "[t]here is no indication that Dr. Rosenzweig has any experience or knowledge on the appropriate testing a medical device manufacturer should undertake." *Huskey*, 29 F. Supp. 3d at 705. That same reasoning continues to apply.

B. Adverse Event Reporting

For similar reasons, this Court also should exclude Dr. Rosenzweig's opinion that "Ethicon's collection and reporting of adverse events and complications to physicians and patients was incomplete, inaccurate and misleading." Ex. C-2, TVT Report No. 2, p. 97. Dr. Rosenzweig's experience as a surgeon does not qualify him to render opinions on adverse event reporting. He has no relevant experience with the FDA or in the medical device industry that would permit him to offer expert testimony regarding the standard of care for collecting and reporting adverse events. *See, e.g.*, *In re Diet Drugs*, MDL No. 1203, 2001 WL 454586, *16 (E.D. Pa. Feb. 1, 2001) (excluding heart surgeon's opinions regarding adverse event reporting

because surgeon had "no experience or expertise in . . . adverse event reporting" and based his opinions on personal belief rather than reliable methodology).

Not surprisingly, because Dr. Rosenzweig has no relevant experience, he is unable to identify a single rule or regulation that would require Ethicon to collect and report adverse events in the manner he suggests it should have. In fact, Dr. Rosenzweig does not identify *any* basis or reason for his opinion, as he must. Instead, his opinion is apparently based purely on personal belief. The Court should exclude his opinion on that basis. *See Hines v. Wyeth*, 2011 WL 2680842, *5 (S.D. W. Va. July 8, 2011) (finding that expert provided no basis for opinions, rendering them inadmissible "personal opinion").

As is the case with his "special patient population" opinion, Dr. Rosenzweig's critique of Ethicon's adverse event reporting amounts to nothing more than a narrative summary of the evidence. Dr. Rosenzweig cites or quotes Ethicon e-mails and company witness depositions purporting to show that Ethicon employees did not know how many complaints were missed by the company's "complaint tracking system." Because the jury does not need an expert witness to read documents and summarize evidence, the Court should exclude Dr. Rosenzweig's opinions regarding adverse event reporting. *See*, *e.g.*, *Hines*, 2011 WL 2680842, at *7 (excluding as "irrelevant" and "unhelpful" expert opinion "based on [the expert's] own reading of defendants' internal documents" that the "jury is more than capable of reading and summarizing"); *In re Fosamax*, 645 F. Supp. 2d at 192 (holding regulatory expert "will not be permitted to merely read, selectively quote from, or 'regurgitate' the evidence").

C. Training

Dr. Rosenzweig claims that Ethicon did not fund and provide appropriate training to physicians concerning the use of TVT-O and TVT-Abbrevo. Ex. C-4, TVT-O Report No. 4, pp. 74-77; Ex. D, TVT-Abbrevo Report, pp. 73-77. Dr. Rosenzweig is not qualified to testify about what

funding and level of training that a medical device manufacturer should provide. Further, his opinions are based on a narrative summary of documents rather than any special expertise. In addition, Dr. Rosenzweig's opinions are irrelevant and prejudicial insofar as he does not claim that a specific Plaintiff's implanting physician was not appropriately trained or competent. *See Cisson*, 948 F. Supp. 2d at 614 (excluding similar opinions about training under similar circumstances).

D. Legal Conclusions

Finally, the Court should disallow any testimony by Dr. Rosenzweig that amounts to a legal conclusion. *See, e.g.*, Ex. C-2, TVT Report No. 2, pp. 28, 72, 77, 84-85 (asserting that Ethicon failed to act like a "reasonable and prudent medical device manufacturer"). As this Court has held, testimony that amounts to a legal conclusion is inadmissible. *See, e.g.*, *Huskey*, 29 F. Supp. 3d at 703.

VI. The Court should preclude Dr. Rosenzweig from criticizing the cut of TVT mesh.

The Court also should preclude Dr. Rosenzweig from suggesting that laser-cut TVT mesh is a safer alternative to mechanically-cut TVT mesh, or vise versa. In his TVT and TVT-O reports, Dr. Rosenzweig opines that fraying, roping, curling, and other deformities are associated with mechanically-cut mesh and posits that laser cutting was a viable solution to correct the fraying, roping, and curling issue. Ex. C-2, TVT Report No. 2 at 41-48. At the same time, however, Dr. Rosenzweig criticizes laser-cut mesh in his TVT-Exact and TVT-Abbrevo and suggests that mechanically-cut mesh is preferable. Ex. D, TVT-Abbrevo Report at 12-13; Ex. E, TVT-Exact Report at 12-13.

First, as set forth in Section II.A, Dr. Rosenzweig is not qualified to provide design opinions. Moreover, Dr. Rosenzweig cannot have it both ways. He cannot simultaneously argue that mechanically-cut mesh is less safe than laser cut-mesh and that laser-cut mesh is less safe than mechanically-cut mesh. If the Court permits Dr. Rosenzweig to offer opinion testimony

critiquing mechanically-cut mesh, it should preclude him from referencing laser-cut mesh as a viable alternative design, as vice versa. *See Huskey*, 29 F. Supp. 3d at 712 (precluding expert from testifying that laser-cut mesh was preferable given vague, noncommittal testimony).

Further, Dr. Rosenzweig's opinions lack a reliable, scientific foundation.[4] Dr. Rosenzweig cites *no* studies in support of his opinions about complications attributable to mechanically-cut mesh. *See* Ex. I, 9/22/15 Rosenzweig Dep. Tr. at 198:18-204:12; *see also id.* at 201:22-202:14. He admits that he knows of no clinical data showing that mechanically-cut TVT mesh is associated with a statistically significantly higher rate of pain or dyspareunia than laser-cut TVT mesh. *See id.* at 201:6-203:2. In fact, he testified that "the only study that directly compared laser cut mesh with mechanical cut mesh showed *a higher rate of erosion in the laser cut mesh*." *Id.* at 200:23-201:5 (emphasis added). In *In re AlloDerm Litig.*, the New Jersey court found that the alternative design requirement was not met when the proposed alternative design was not shown to be safer and feasible through testing or literature. *See* Ex. L (*Alloderm* Design Defect Order) at 29-32. Because Dr. Rosenzweig acknowledges that he is unaware of any testing or literature supporting his laser-cut mesh opinion, the Court can and should exclude that opinion.

VII. The Court should preclude Dr. Rosenzweig from testifying about certain alleged complications associated with TVT-Abbrevo.

In his TVT-Abbrevo report, Dr. Rosenzweig states that "the shorter length of the laser cut mesh in the TVT Abbrevo leads to more complications." Ex. D, TVT-Abbrevo Report at 13. Dr. Rosenzweig cites no studies in support of his conclusory statement. It appears that it is based solely on one internal Ethicon document, which lends no support to the statement. Ex.P,

[4] From a clinical standpoint, Dr. Rosenzweig has no knowledge of ever implanting a patient with laser cut mesh. Thus, he lacks the ability to opine based on "experience" that there is a difference in outcome regarding the two. *See* Ex. Q, Rosenzweig 3/24/14 Dep. Tr. 174:13-22, 176:20-24.

ETH.MESH.09911296. Given the utter lack of methodology in support of Dr. Rosenzweig's assertion, the Court should reject it as unreliable.

VIII. The Court should not allow other opinions that are beyond Dr. Rosenzweig's expertise and/or otherwise improper.

Dr. Rosenzweig's reports are replete with other statements about Ethicon's alleged knowledge and conduct. *See, e.g.,* Ex. C-2, TVT Report No. 2, pp. 2, 30, 39, 43, 48, 49, 61, 68, 70, 72, 75, 76, 80 (discussing what Ethicon allegedly "knew"); Ex. C-5, TVT Report No. 5, p. 3 ("[B]ecause of its economic interest in maintaining its competitive advantage in the MUS market . . . Ethicon put profits before patient safety"). This Court has consistently found that experts in this MDL, including Dr. Rosenzweig, may not testify about device manufacturers' "knowledge, state of mind, alleged bad acts, failures to act, and corporate conduct and ethics." *Cisson*, 948 F. Supp. 2d at 611; *Huskey*, 29 F. Supp. 3d at 703.

The Court should similarly preclude Dr. Rosenzweig from testifying about alleged bias. For instance, Dr. Rosenzweig seeks to opine that Dr. Ulmsten had a financial interest the development of TVT and that Ethicon should have disclose this. Ex. C-1, TVT Report No. 1, pp. 87-94. Notably, Dr. Rosenzweig is not complaining that the results of the Ulmsten studies are incorrect. There is no indication that Dr. Rosenzweig has any qualifications to discuss the potential bias that a financial incentive may play in medical research or that he has any peculiar experience in biostatistics. More importantly, he offers no methodology. All Dr. Rosenzweig does is provide a narrative summary of events which would not be helpful for the jury.

The Court should also preclude Dr. Rosenzweig from testifying about cancer and other complications that a respective Plaintiff has not had and that no competent physician has testified that the Plaintiff likely will sustain. *See* Ex. C-2, TVT Report No. 2, pp. 78-83; Ex. M, *Bellew v.*

Ethicon, Inc., No. 2:13-cv-22473, Order at 20 (S.D. W. Va. Nov. 20, 2014) ("Evidence of complications that the plaintiff did not experience is irrelevant and lacking in probative value").

Finally, the Court should find that Ethicon may reserve for trial objections to Dr. Rosenzweig's testimony that are based merely on a narrative summary of Ethicon documents. *See, e.g.*, Ex. C-1, TVT Report No. 1, pp. 32-35, 39-61; *Hershberger v. Ethicon Endo-Surgery, Inc.*, 2012 WL 524442, at *8 (S.D. W. Va. Feb. 15, 2012) (excluding expert testimony based on defendant's corporate documents); *Hines v. Wyeth*, No. 2:04-0690, 2011 WL 2680842, at *5 (S.D. W. Va. July 8, 2011) (excluding expert testimony in part because it "merely regurgitates factual information that is better presented directly to the jury rather than through the testimony of an expert witness").

CONCLUSION

For the above reasons, Defendants respectfully request that the Court grant their Motion to Exclude the Testimony of Bruce Rosenzweig, M.D.

Respectfully Submitted,

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IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES TO ETHICON WAVE 1 CASES	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

CERTIFICATE OF SERVICE

I, Christy D. Jones, certify that on April 21, 2016, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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